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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/581,651	10/10/2000	Seth Lawrence Schor	002.00120	4652

5100 7590 05/03/2002

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EXAMINER	
RAWLINGS, STEPHEN L	

ART UNIT	PAPER NUMBER
1642	19

DATE MAILED: 05/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/581,651	Applicant(s) SCHOR ET AL.	
	Examiner Stephen L. Rawlings, Ph.D.	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 March 2002* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-59* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Notice to Comply* .

DETAILED ACTION

1. The amendment filed October 10, 2000 in Paper No. 7 is acknowledged and has been entered. Claims 3-8, 13, 24, 35, 39, 44, 47, 49, and 51-58 have been amended. Claim 59 has been added.

2. The amendment filed July 26, 2001 in Paper No. 9 is acknowledged and has been entered.

3. The amendment filed March 27, 2002 in Paper No. 17 is acknowledged and has been entered.

4. Claims 1-59 are pending in the application and are currently subject to restriction and an election requirement.

Sequence Rules Compliance

5. The communication filed March 27, 2002 in Paper No. 17 is not fully responsive to the Office communication mailed June 21, 2001 (Paper No. 8) for the reason(s) set forth on the attached Notice To Comply With The Sequence Rules and in the paragraph below. Applicants must comply with the requirements of the sequence rules (37 CFR §§ 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132.

In particular, it is noted that the application fails to meet the requirements of 37 CFR §§ 1.821-1.825 for the following reasons:

(a) Claims 27 and 28 recite amino acid sequences that are not identified by sequence identification numbers corresponding to same amino acid sequences set forth in the Sequence Listing.

(b) Figure 2 depicts two amino acid sequences that are not identified by sequence identification numbers corresponding to same amino acid sequences set forth in the Sequence Listing.

(c) Figure 3 depicts multiple amino acid sequences that are not identified by sequence identification numbers corresponding to same amino acid sequences set forth in the Sequence Listing.

In replying to this Office Action Applicants are requested to correct any further deficiencies, which have not been specifically identified. If necessary to correct the deficiencies, Applicants are required to submit paper and computer-readable copies of a substitute Sequence Listing, together with a statement that both copies are the same and that no new matter has been entered.

Since the reply appears to be *bona fide* attempt to comply with the requirements of the sequence rules (37 CFR §§ 1.821-1.825), Applicants are given the same period of time within which to reply to this Office Action to correct the deficiency so as to comply with the sequence rules (37 CFR §§ 1.821-1.825) in order to avoid abandonment of the application under 37 CFR § 1.821(g).

Election/Restrictions

6. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions that are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-13, 27, 29, 51, 54, 56, 57, and 59, drawn to a nucleic acid molecule encoding a polypeptide, a vector comprising said nucleic acid molecule, a host cell comprising said vector, a polypeptide encoded by said nucleic acid molecule, a method for producing said polypeptide, an agent comprising said polypeptide, and a pharmaceutical composition comprising said polypeptide.

Group II, claim(s) 14-18, 24, 25, 45, and 46, drawn to an antibody that binds specifically to the polypeptide of SEQ ID NO: 1.

Group III, claim(s) 19-24 and 26, drawn to an antibody that binds specifically to fibronectin.

Group IV, claim(s) 28 and 30, drawn to a molecule.

Group V, claim(s) 31-35, drawn to a nucleic acid molecule.

Group VI, claim(s) 36-39 and 44, drawn to a method for diagnosing, assessing risk, or determining a prognosis.

Group VII, claim(s) 40-44, drawn to a method for diagnosing, assessing risk, or determining a prognosis.

Group VIII, claim(s) 47-50, 52, 53, 55, and 58, drawn to a method for modulating, healing, or preventing.

7. The inventions listed as groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature of group I is producing a nucleic acid molecule encoding a polypeptide having the amino acid sequence set forth in SEQ ID NO: 1.

The special technical feature of group II is producing an antibody that binds specifically to the polypeptide of SEQ ID NO: 1.

The special technical feature of group III is producing an antibody that binds specifically to fibronectin.

The special technical feature of group IV is producing a molecule that stimulates production of antibodies that bind specifically to fibronectin.

The special technical feature of group V is producing a nucleic acid molecule that selectively hybridizes to a nucleic acid molecule to thereby distinguish a nucleic acid molecule comprising a polynucleotide sequence that encodes the polypeptide of SEQ ID NO: 1 from a nucleic acid molecule comprising a polynucleotide sequence that encodes fibronectin.

The special technical feature of group VI is detecting a polypeptide.

The special technical feature of group VII is detecting a nucleic acid molecule.

The special technical feature of group VIII is administering a polypeptide.

Accordingly, groups I-VIII are not linked by the same or corresponding special technical feature so as to form a single general inventive concept. Furthermore, PCT Rules 13.1 and 13.2 do not provide for a single general inventive concept comprising more than the first claimed product, more than the first claimed method for producing said product, or more than the first claimed method for using said product.

8. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Group I, Species A-E: Claim 27 is generic to a plurality of species comprising a peptide comprising an amino acid sequence selected from the group consisting of (a) SEQ ID NO: 3, (b) SEQ ID NO: 4, (c) SEQ ID NO: 5, (d) SEQ ID NO: 6, and (e) SEQ ID NO: 7, as set forth in claim 29.

Group II, Species A-E: Claims 14-17 are generic to a plurality of species comprising an antibody reactive towards a molecule comprising a peptide comprising an amino acid sequence selected from the group consisting of (a) SEQ ID NO: 3, (b) SEQ ID NO: 4, (c) SEQ ID NO: 7, (d) SEQ ID NO: 14, and (e) SEQ ID NO: 15, as set forth in claim 18.

Group III, Species A-F: Claims 19-22 are generic to a plurality of species comprising an antibody reactive towards a peptide comprising an amino acid sequence selected from the group consisting of (a) SEQ ID NO: 8, (b) SEQ ID NO: 9, (c) SEQ ID NO: 10, (d) SEQ ID NO: 11, (e) SEQ ID NO: 12, and (f) a specifically identified amino acid sequence derived from the amino acid sequence of a C-terminal fragment of fibronectin, as set forth in claim 23.

Note: If Applicants elect species F in replying to this Office Action, Applicants are required to specifically identify the particular amino acid sequence of the peptide to which the claims are to be drawn.

Group IV, Species A-F: Claim 28 is generic to a plurality of species comprising a peptide comprising an amino acid sequence selected from the group consisting of (a) SEQ ID NO: 8, (b) SEQ ID NO: 9, (c) SEQ ID NO: 10, (d) SEQ ID NO: 11, (e) SEQ ID NO: 12, and (f) a specifically identified amino acid sequence derived from the amino acid sequence of a C-terminal fragment of fibronectin, as set forth in claim 30.

Note: If Applicants elect species F in replying to this Office Action, Applicants are required to specifically identify the particular amino acid sequence of the peptide to which the claims are to be drawn.

9. Applicants are required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

10. Upon the allowance of a generic claim, Applicants will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, Applicants must indicate which are readable upon the elected species. MPEP § 809.02(a).

11. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

Group I, Species A-E:

The special technical feature of species A is producing a polypeptide comprising the amino acid sequence set forth in SEQ ID NO: 3.

The special technical feature of species B is producing a polypeptide comprising the amino acid sequence set forth in SEQ ID NO: 4.

The special technical feature of species C is producing a polypeptide comprising the amino acid sequence set forth in SEQ ID NO: 5.

The special technical feature of species D is producing a polypeptide comprising the amino acid sequence set forth in SEQ ID NO: 6.

The special technical feature of species E is producing a polypeptide comprising the amino acid sequence set forth in SEQ ID NO: 7.

Accordingly, species A-E of the invention of group I do not share the same or corresponding special technical feature so as to form a single general inventive concept.

Group II, Species A-E:

The special technical feature of species A is producing an antibody reactive towards a polypeptide comprising the amino acid sequence set forth in SEQ ID NO: 3.

The special technical feature of species B is producing an antibody reactive towards a polypeptide comprising the amino acid sequence set forth in SEQ ID NO: 4.

The special technical feature of species C is producing an antibody reactive towards a polypeptide comprising the amino acid sequence set forth in SEQ ID NO: 7.

The special technical feature of species D is producing an antibody reactive towards a polypeptide comprising the amino acid sequence set forth in SEQ ID NO: 14.

The special technical feature of species E is producing an antibody reactive towards a polypeptide comprising the amino acid sequence set forth in SEQ ID NO: 15.

Accordingly, species A-E of the invention of group II do not share the same or corresponding special technical feature so as to form a single general inventive concept.

Group III, Species A-F:

The special technical feature of species A is producing an antibody reactive towards a polypeptide comprising the amino acid sequence set forth in SEQ ID NO: 8.

The special technical feature of species B is producing an antibody reactive towards a polypeptide comprising the amino acid sequence set forth in SEQ ID NO: 9.

The special technical feature of species C is producing an antibody reactive towards a polypeptide comprising the amino acid sequence set forth in SEQ ID NO: 10.

The special technical feature of species D is producing an antibody reactive towards a polypeptide comprising the amino acid sequence set forth in SEQ ID NO: 11.

The special technical feature of species E is producing an antibody reactive towards a polypeptide comprising the amino acid sequence set forth in SEQ ID NO: 12.

The special technical feature of species F is producing an antibody reactive towards a polypeptide comprising a specifically identified amino acid sequence derived from the amino acid sequence of a C-terminal fragment of fibronectin according to claim 23.

Accordingly, species A-F of the invention of group III do not share the same or corresponding special technical feature so as to form a single general inventive concept.

Group IV, Species A-F:

The special technical feature of species A is producing an immunogen comprising the amino acid sequence set forth in SEQ ID NO: 8.

The special technical feature of species B is producing an immunogen comprising the amino acid sequence set forth in SEQ ID NO: 9.

The special technical feature of species C is producing an immunogen comprising the amino acid sequence set forth in SEQ ID NO: 10.

The special technical feature of species D is producing an immunogen comprising the amino acid sequence set forth in SEQ ID NO: 11.

The special technical feature of species E is producing an immunogen comprising the amino acid sequence set forth in SEQ ID NO: 12.

The special technical feature of species F is producing an immunogen comprising a specifically identified amino acid sequence derived from the amino acid sequence of a C-terminal fragment of fibronectin according to claim 23.

Accordingly, species A-F of the invention of group IV do not share the same or corresponding special technical feature so as to form a single general inventive concept.

12. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

13. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (703) 305-3008. The examiner can normally be reached on Monday-Thursday, alternate Fridays, 8:00AM-5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1642

DONNA WORTMAN
PRIMARY EXAMINER

slr
May 1, 2002

Notice to Comply	Application No.	Applicant(s)	
	09/581,651	SCHOR ET AL.	
	Examiner	Art Unit	
	Stephen L. Rawlings, Ph.D.	1642	

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☒ 7. Other: Applicants are required to comply with the requirements set forth under 37 CFR 1.821-1.825 before this application will be examined. If it is necessary, Applicants are required to submit substitute paper and computer-readable copies of the Sequence Listing. See attached explanation.

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
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